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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,220	04/17/2008	Catherine Ronin	BJS-1487-29	5743

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
HUYNH, PHUONG N	
ART UNIT	PAPER NUMBER
1644	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,220	RONIN ET AL.	
	Examiner	Art Unit	
	PHUONG HUYNH	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/2/06*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *49-100* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 49-100 are pending.

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

When Claims Are Directed to Multiple Categories of Inventions:

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1)A product and a process specially adapted for the manufacture of said product; or

(2)A product and process of use of said product; or

(3)A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4)A process and an apparatus or means specifically designed for carrying out the said process; or

(5)A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 73-74, drawn to a process for screening glycoform specific antibodies directed against a specific glycoform of TSH.

II. Claims 73, drawn to a process for screening glycoform specific antibodies directed against a specific glycoform of LH.

III. Claims 73, drawn to a process for screening glycoform specific antibodies directed against a specific glycoform of FSH.

IV. Claims 73, drawn to a process for screening glycoform specific antibodies directed against a specific glycoform of placental hCG.

V. Claims 76-80, drawn to a process for the preparation of a specific glycoform of a recombinant human TSH produced by mammalian cells.

VI. Claim 81-91 and 100, drawn to a specific glycoform of recombinant human TSH.

VII. Claims 92-95, drawn to a kit for assaying a specific glycoform of a first glycoprotein, characterized in that it comprises at least one specific antibody elicited against a first glycoprotein, and at least one glycoform of a second glycoprotein, said second glycoprotein being itself a glycoform of the first glycoprotein, wherein said glycoform of the second glycoprotein is selected from a group of glycoforms of the second glycoprotein, each glycoform of said group corresponding to a determined glycosylation state defined by a determined branching state and a determined fucosylation and/or sialylation state.

VIII. Claim 96, drawn to a method for calibrating TSH immunoassays comprising the use of a specific glycoprotein selected from the list comprising: a glycoform of recombinant human TSH produced by mammalian cells which is substantially less sialylated than said recombinant human TSH, a glycoform of recombinant human TSH produced by mammalian cells which is substantially more sialylated and/or less fucosylated than said recombinant human TSH, and a glycoform of recombinant human TSH.

Linking claims 49-72, 75 and 97-99 will be examined along with Groups I-IV if any one of said Groups is elected.

Claims 49-72 and 75 links inventions I-IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 49-72 and 75. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The Groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-IV lack unity of invention because the groups do not share same or corresponding technical feature. The processes of selecting antibodies that bind to different glycoproteins that differ with respect to the binding specificity of the antibodies, the different glycosylation state and/or branching of the glycoprotein hormones TSH, LH, FSH or hCG.

Groups I and V-VIII lack unity of invention because even though the inventions of these groups require the technical feature of recombinant human TSH, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of Papandreou et al (Molecular and Cellular Endocrinology 73: 15-26, 1990; PTO 1449), Szudlinski et al (Endocrinology 133: 1490-1503, 1993; PTO 1449) and (J Clinical Endocrinology and Metabolism 77(2): 393-398; PTO 892).

Papandreou et al (Molecular and Cellular Endocrinology 73: 15-26, 1990; PTO 1449) teach a method of screening glycoform specific antibodies directed against native (first glycoprotein) and deglycosylated human TSH (second glycoprotein being itself less glycosylated form of first glycoprotein) (see entire document, page 18, in particular) or glycosylated TSH (see page 23, col. 1, in particular). Papandreou et al teach the importance of noting among the glycosylation-dependent epitopes of TSH

antibodies in assaying biologically active TSH in human blood samples (see paragraph bridging page 2425, in particular).

Panpandreou et al do not teach the glycoform of the second TSH is fucosylated or sialyated.

However, Szudlinski et al teaches recombinant human thyrotropin TSH and a process of producing such (see page 1491, col. 2, in particular). Szudlinski et al teaches a process of determining the glycosylation state of rhTSH such as sialylation state and/or fucosylation state of rhTSH (see page 1494, Table 2, carbohydrate composition analysis, page 1496, in particular).

Papandreou et al (J Clinical Endocrinology and Metabolism 77(2): 393-398; PTO 892) teach a process of determining branching state of TSH using Con A lectin affinity chromatograph (see entire document, page 394, col. 1, Fig 1, in particular). Papandreou et al teaches N-linked oligosaccharide structures were shown to interact with Con A according to their branching properties (see Fig 1, in particular). Papandreou et al further teach both TSH carbohydrates branching and sialyation may vary in different clinical conditions and/or TSH biological activity (see abstract, page 397, in particular).

Therefore, it would have been obvious to one of ordinary skilled in the art at the time the invention was made with the expectation of success to screen for antibodies directed to different glycoforms of rhTSH Papandreou et al using the sialyated or fucosylated rhTSH as taught by Szudlinski et al and branching state of TSH as taught by Papandreou et al.

One of ordinary skill in the art would motivated with to do this because TSH carbohydrate branching and sialyation may vary in different clinical conditions and/or TSH biological activity as taught by Papandreou et al (J Clinical Endocrinology and Metabolism 77(2): 393-398; 1999; page 397, in particular).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention.

Accordingly, Groups I-VIII are not so linked as to form a single general inventive concept and restriction is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, Ph.D. whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Thursday from 9:00 a.m. to 6:30 p.m. and alternate Friday from 9: 00 a.m. to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B O'Hara can be reached on (571) 272-0878. The IFW official Fax number is (571) 273-8300.

Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong Huynh/
Primary Examiner, Art Unit 1644
September 12, 2008